

REMARKS

Claims 34-47 remain pending in this application. Claims 34, 37, 42, 43, 46 and 47 are allowed. Claims 35, 36, 38-41, 44 and 45 are rejected.

The provisional rejection of claim 36 under 35 USC 101 as claiming the same invention as copending Application No. 10/354,207 has been maintained. Claim 37 is now pending in the '207 filing. Currently pending claim 37 of '207 is an open-ended claim directed to the compound of structure (6), which is an enantiomer of GS-7340. As the examiner correctly points out, structure (6) also is a feature of claim 36 of the instant case. However, the Examiner is respectfully requested to reconsider the position that this necessarily makes claim 36 here the "same invention" as in claim 37 of '207.

A claim directed to a "compound," without more, includes any other substance. So, for example, the compound of structure (6) as recited in '207 could include (i.e., does not exclude) any other thing – other compounds, containers, reagents, devices, substances, etc. It is compound (6) plus, theoretically, the entire world. As such, it is an open-ended claim such as a "comprising" claim. See M.P.E.P 2111.03, copy attached. It therefore does not exclude (i.e., includes) any other enantiomer of compound (6). Thus claim 37 is broader than claim 36 here, which expressly states that the compound (6) is "diastereomerically enriched." These claims are not directed to the same invention. Claim 37 of '207 includes the ordinary racemate, whereas claim 36 here is enriched in the compound (6) enantiomer. The claims are different in the amount of "contaminant" they are permitted to embrace. The Examiner is focusing on the structure and not taking into account the language "diastereomerically enriched" found in claim 36.

The Examiner is respectfully requested to reconsider and withdraw this rejection.

PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

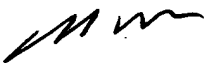
Claims 35 and 44-45 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application Nos. 11/031,228; 11/031,250; 11/031,251 and 11/031,252. It is applicants' intention to permit these 4 cases to go abandoned. In any case, once this case is found to be allowable and issues, double patenting rejections will mature in these 4 applications. However, this will not prevent the issuance of the instant application. It is not necessary to file any terminal disclaimer in THIS case in order to advance the case to issue. Should the double patenting issue remain in the 4 copending applications after grant of the instant case, a terminal disclaimer may be appropriate in those cases. It is not, however, necessary in the present application.

NEW GROUND OF OBJECTION

Claims 38-41 were objected to under 37 CFR 1.75(c) as being in improper form for referring to other claims with the conjunction "and". These claims have been amended to recite the multiple dependency in the alternative.

This application is now believed to be in condition for allowance. An early Notice to that effect is solicited.

Respectfully submitted,



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apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

2111.03 Transitional Phrases [R-2]

The transitional phrases "comprising", "consisting essentially of", and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.

The transitional term "comprising", which is synonymous with "including", "containing", or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Molecular Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as: "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated there-

with"). >But see *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331-32, 70 USPQ2d 1508, 1516 (Fed. Cir. 2004) (holding that a bone repair kit "consisting of" claimed chemicals was infringed by a bone repair kit including a spatula in addition to the claimed chemicals because the presence of the spatula was unrelated to the claimed invention). <A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986).

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103;

absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.); *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re DeLajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.")

OTHER TRANSITIONAL PHRASES

Transitional phrases such as "having" must be interpreted in light of the specification to determine

whether open or closed claim language is intended. See, e.g., *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001) (term "having" in transitional phrase "does not create a presumption that the body of the claim is open"); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997) (In the context of a cDNA having a sequence coding for human PF, the term "having" still permitted inclusion of other moieties). The transitional phrase "composed of" has been interpreted in the same manner as either "consisting of" or "consisting essentially of," depending on the facts of the particular case. See *AFG Industries, Inc. v. Cardinal IG Company*, 239 F.3d 1239, 1245, 57 USPQ2d 1776, 1780-81 (Fed. Cir. 2001) (based on specification and other evidence, "composed of" interpreted in same manner as "consisting essentially of"); *In re Bertsch*, 132 F.2d 1014, 1019-20, 56 USPQ 379, 384 (CCPA 1942) ("Composed of" interpreted in same manner as "consisting of," however, court further remarked that "the words 'composed of' may under certain circumstances be given, in patent law, a broader meaning than 'consisting of'").

2112 Requirements of Rejection Based on Inherency; Burden of Proof

[R-2]

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).